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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	114474-14-FESI00002US	5214

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EXAMINER	
SAYOC, EMMANUEL	
ART UNIT	**PAPER NUMBER**
3746	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,762	YANASE ET AL.	
	Examiner	Art Unit	
	Emmanuel Sayoc	3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2000 and 09 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the RCE and amendments received on 1/27/2005. Claim prosecution is re-opened under the applicant's request for continued examination. In making the below rejections and/or objections the examiner has considered and addressed each of the applicants arguments. Claims 2, 4, and 5 have been cancelled. Claims 1, 3, and 6-11 are pending and under current consideration.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136), and in further view of Ito (U.S. 5,063,025), and Akaike et al. (U.S. 5,061,247).

With respect to claims 1, and 3, Trull et al., in Figure 6, disclose a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction (labeled by the examiner on Figure 6 attached to the end of this office action) is provided, and a periphery of a bottom surface

of the gasket that is not in contact with the liquid is formed into a tapered slant (also labeled by the examiner on Figure 6).

The Trull et al. differs from the claimed invention in that there is no disclosure of one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin. Ito, in column 5 lines 1-7, discloses that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (TEFLON). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene or polypropylene, as taught by Ito, in order to achieve optimum gasket lubrication, functionality, and protection within a syringe device.

The Trull et al. differs from the claimed invention in that there is no disclosure of to the gasket being made integrally of a material with JIS hardness of 55 to 60. Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is suitable for gaskets applied to syringe devices. This general range covers the applicants claimed range. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device. With respect to the specific range of JIS hardness 55 to 60, where the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136. Other than the range being preferred for presumably general optimum device function, the applicant has provided no criticality or unexpected or non-obvious advantage over choosing one this particular range. The coating taught by the prior art is integral in that the coating and the plunger coated form an integral plunger assembly.

With respect to claim 3, the Trull et al. apparatus comprises a tapered slant with a first and second plunger diameter. The examiner has labeled these embodiments on the marked up Figure 6.

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about 5mm. Furthermore, with respect to claims 6-8, there is no disclosure of the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claim 3 and 6-8, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

With respect to claims 9 and 10, a second tapered (see examiner's marked up Figure 6) slant is formed between the peripheral side surface of the gasket (70) that is in contact with an inner surface of the syringe barrel (60) and the restriction (see examiner's marked up Figure 6). The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus, in this case a contrast medium, does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Ito and Akaike, as applied to claims 1 or 9, and in further view of Higashikawa (U.S. 5,830,193).

Trull et al., as modified by Ito, set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the syringe including a lure lock. Higashikawa in Figure 1a-1c, 7a, and 7b, teaches that lure lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32) – see column 7 line 49. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, device by incorporating the lure locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

Response to Arguments

5. Applicant's arguments filed 1/27/2005 have been fully considered but they are not persuasive. The prior art that shows it was well known to coat syringe gaskets or plungers with polyethylene or polypropylene, as taught by Ito. The prior art references are in the same filed of endeavor as that of the claimed invention, syringe plungers. Providing a protective coating to a plunger is a relevant solution to a problem within the field of endeavor of any syringe device with a plunger. The two prior art references, Trull et al. and Ito, are drawn to two syringe plungers classified in the same class. The fact that one syringe is used in a different application as the other does not make them non analogous. The combination above was made with the motivation of providing a protective coating to the base reference. Applicant has not provided convincing arguments or evidence that this motivation is not valid. The fact that the prior art combination solves a different problem or has a different motivation to combine than that of the claimed invention is irrelevant. The combination outlined arrives at the applicant's claimed invention. Applicant states that the superelastic material teaches away from a gasket made of hard material. This argument lacks evidence and is therefore not persuasive. Rejections are proper and are therefore sustained.

6. This office action is being made non-final to afford the applicant the opportunity to respond to the new grounds of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited to further show the state of the art with respect to gaskets for syringes.

U.S. Pat. 5, 688, 252 to Matsuda et al. – teaches the general nature of the art of syringe gaskets

U.S. Pat. 5, 397, 313 to Gross – teaches the general nature of the art of syringe gaskets

U.S. Pat. 4, 303, 070 to Ichikawa et al. – teaches the general nature of the art of syringe gaskets

U.S. Pat. 4,474,071 to Marteau d' Autry – teaches a coating for protection.

JP 56-119765 to Showa Denko – teaches particular attention to the coating hardness in a piston.

Contact Information

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emmanuel Sayoc whose telephone number is (571) 272 4832. The examiner can normally be reached on M-F 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Thorpe can be reached on (571) 272-4444. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Emmanuel Sayoc
Examiner
Art Unit 3746

ECS

Timothy S. Thorpe
Supervisory Patent Examiner
Group 3700

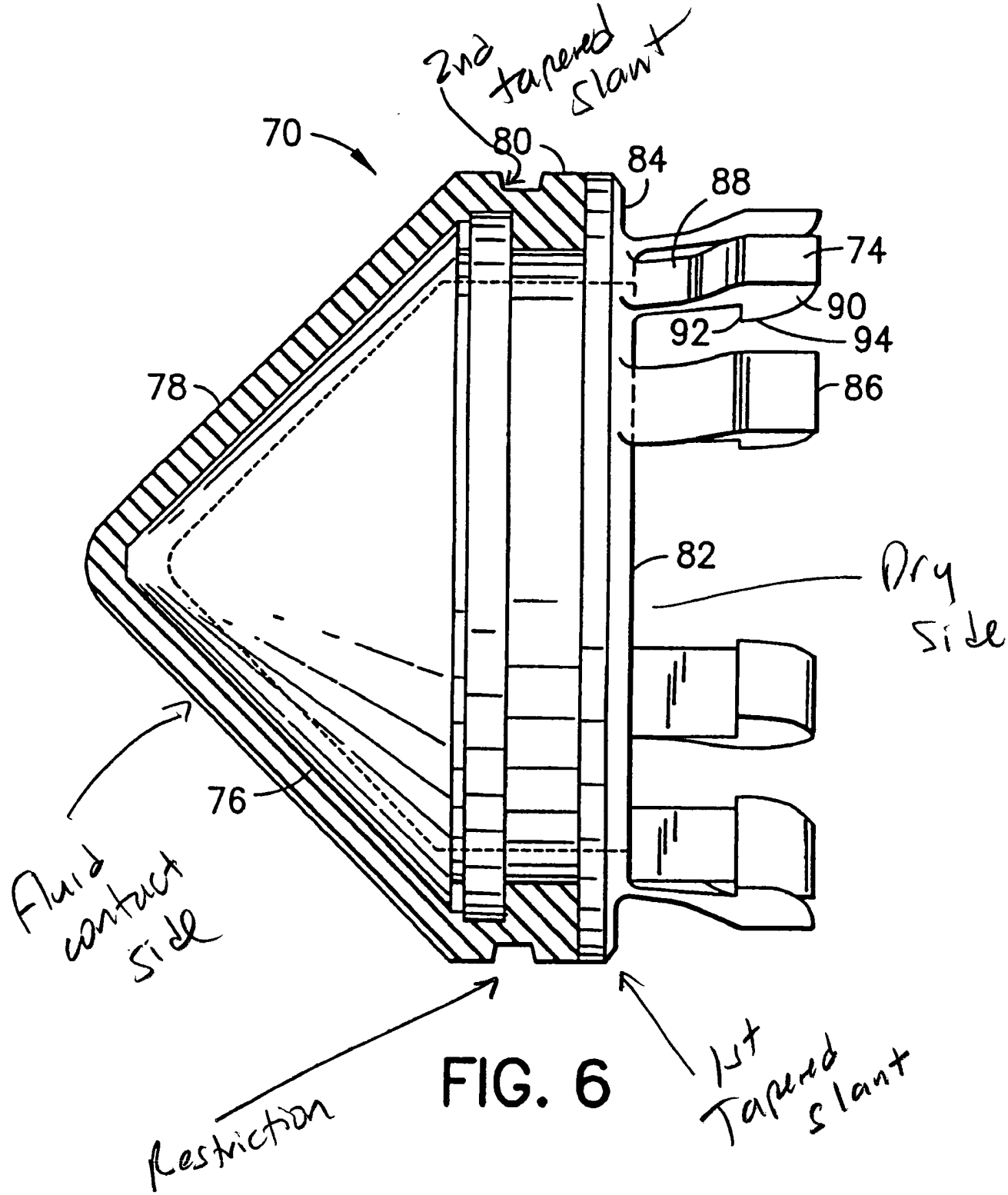

FIG. 6

examiner's marked Figure
Please Include in Office Action